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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,661	08/09/2007	Ken Kato	MUR-050-USA-PCT	1645
27955	7590	06/02/2010	EXAMINER	
TOWNSEND & BANTA c/o PORTFOLIO IP PO BOX 52050 MINNEAPOLIS, MN 55402			KENNEDY, NICOLETTA	
			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			06/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,661	Applicant(s) KATO ET AL.	
	Examiner Nicoletta Kennedy	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/24/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/10 has been entered.

Status of Claims

2. Claims 1-9 are pending. Claims 5-7 are withdrawn as drawn to a nonelected invention. Claims 8-9 are newly added.

Withdrawn Rejections

3. The rejection of claims 1-2 under 35 U.S.C. 102(b) over Yukihiro et al. (JP 2001-158736) (pub. June 12, 2001) is withdrawn in view of Applicant's amendments.

4. The rejection of claim 2 under 35 U.S.C. 102(e) over Kanamaru et al. (US 2006/0240115) is withdrawn in view of Applicant's amendments.

5. The rejection of claim 3 under 35 U.S.C. 103(a) over Msika et al. (US 7,511,010) in view of Nieuwenhuizen (US 2006/0134182) is withdrawn in view of Applicant's amendments.

6. The rejection of claim 4 under 35 U.S.C. 103(a) over Nieuwenhuizen (US 2006/0134182) in view of Greff et al. (FR 2692781) is withdrawn in view of Applicant's amendments.

New Claim Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Nieuwenhuizen (WO 2004/064819) (filed Jan. 20, 2004) as evidenced by Milk Nutrition Facts (Food and Nutrition Service, USDA).

Regarding claims 1-2 and 9, Nieuwenhuizen teaches that certain sphingolipids, particularly sphingomyelin, are already naturally present in foods which are eaten by many mammals such as cow milk (p. 11). For example, nonfat dry milk contains approximately 0.004% by weight of sphingosine and the total amounts of sphingomyelin and sphingosine in milk are approximately equal (p. 11). Therefore, Nieuwenhuizen teaches that nonfat dry milk is comprised of 0.004% by weight sphingomyelin and that this is present in animal feed. Nonfat dry milk is also comprised of iron and vitamin C (p. 1).

Regarding claims 1-4 and 8-9, the claim preamble claims a skin moisturizer and skin beautifier. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use does not result in a structural difference.

Therefore, Nieuwenhuizen anticipates claims 1-2 and 9.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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12. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Nieuwenhuizen (WO 2004/064819) (filed Jan. 20, 2004) as evidenced by Milk Nutrition Facts (Food and Nutrition Service, USDA).

Regarding claims 1-2 and 9, Nieuwenhuizen teaches that certain sphingolipids, particularly sphingomyelin, are already naturally present in food which are eaten by many mammals such as cow milk (p. 11). For example, nonfat dry milk contains approximately 0.004% by weight of sphingosine and the total amounts of sphingomyelin and sphingosine in milk are approximately equal (p. 11). Therefore, Nieuwenhuizen teaches that nonfat dry milk is comprised of 0.004% by weight sphingomyelin and that this is present in animal feed. Nonfat dry milk is also comprised of iron and vitamin C (p. 1). However, Nieuwenhuizen fails to teach the narrowed range of claim 8. The MPEP cures this deficiency.

MPEP 2144.05 states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" quoting *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have modified the amount of sphingomyelin present . One would have been motivated to do so to use the least amount possible to still achieve the desired result.

Regarding claims 1-4 and 8-9, the claim preamble claims a skin moisturizer and skin beautifier. During examination, statements in the preamble reciting the purpose or

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intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use does not result in a structural difference.

13. Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yukihiro et al. (JP 2001-158736) (pub. June 12, 2001).

Regarding claims 1-4 and 8, Yukihiro et al. teach a feed comprising sphingomyelin (translated detailed description, paras. 0001, 0005, 0008 and 0012). The sphingomyelin may be derived from cow's milk (para. 0007-0008 and 0012). The drink or feed was administered orally to human patients (para. 0025 and 0035). However, Yukihiro et al. do not teach that the sphingomyelin is present within the claimed ranges. The MPEP cures this deficiency.

MPEP 2144.05 states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" quoting *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have modified the amount of sphingomyelin present. One would have been motivated to do so to use the least amount possible to still achieve the desired result.

Regarding claims 1-4 and 8-9, the claim preamble claims a skin moisturizer and skin beautifier. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use does not result in a structural difference.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yukihiro et al. (JP 2001-158736) (pub. June 12, 2001) as applied to claims 1-4 and 8 and further in view of Nieuwenhuizen (WO 2004/064819) (filed Jan. 20, 2004).

Regarding claims 1-4 and 8, the Yukihiro et al. in view of the MPEP teach each limitation of the claims. Yukihiro et al. teach that the formulation may further comprise vitamins D and/or K. However, Yukihiro et al. fail to teach that the formulation further comprises collagen, vitamin C and/or iron. Nieuwenhuizen cures this deficiency.

Regarding claim 9, Nieuwenhuizen teaches a food comprising a sphingolipid, including sphingomyelin wherein the feed may further comprise vitamin C, D or K (p. 4, 11 and 14). The feed may also comprise iron (p. 14).

It would have been prima facie obvious to a person of ordinary skill in the art to have combined the teachings of Yukihiro et al. in view of the MPEP with those of Nieuwenhuizen to substitute vitamin C for vitamin D or K. One would have been motivated to do so because Nieuwenhuizen teaches that vitamins and minerals may be

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added to nutritional supplements and that these vitamins and minerals include vitamins C, D and K.

Regarding claims 1-4 and 8-9, the claim preamble claims a skin moisturizer and skin beautifier. During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use does not result in a structural difference.

Response to Arguments

15. Applicant's arguments filed 4/24/10 have been fully considered but they are not persuasive. Applicant argue unexpected results based on the administration of sphingomyelin. However, the examiner does not dispute that sphingomyelin indeed acts as a moisturizer. As previously stated, the examiner believes this to be an inherent property of sphingomyelin. The results do not illustrate, with regard to the claimed range, that a particular range is needed, nor that administering a large dose as compared to the claimed range would not achieve the desired results.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is

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(571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./

Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611